IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION

ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY, *Plaintiffs*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency, *Defendants*.	Case No.: 4:21-cv-00003-BMM-JTJ The Honorable Brian Morris, Chief Judge

DECLARATION OF MARGARET KARAGAS, PHD

I, Margaret Karagas, declare as follows:

1. My name is Margaret Karagas. I am the James W. Squires Professor and Chair of the Department of Epidemiology and Professor of Community and Family Medicine at Dartmouth Geisel School of Medicine in Hanover, New Hampshire. I also serve as the Director of the Children's Environmental Health and Disease Prevention Research Center and the Center for Molecular Epidemiology at

Dartmouth. I received my PhD from the University of Washington. I have authored or co-authored over 400 articles on a range of topics in epidemiology.

2. My research focuses on identifying emerging environmental exposures, host factors, and mechanisms that impact health from infancy to adult life, and applying novel methods and technologies to understand disease pathogenesis. My current research includes population-based studies of the increase in the incidence rates of keratinocyte cancers in the United States over time and the contribution of widespread exposures such as indoor tanning and drinking water contaminants. Through the Children's Environmental Health and Disease Prevention Research Center, I established a cohort of pregnant women and their offspring in New Hampshire to assess the sources and potential health impacts of arsenic and other factors on childhood infection, allergy/atopy, growth, and neurodevelopment. Research using this cohort will entail multiple collaborative studies of exposure biomarkers, individual susceptibility, and biological response to environmental agents including the developing microbiome and immune response.

3. I am a member of Environmental Defense Fund because I believe in its mission to advocate for science-informed policy and decision making, and to promote measures necessary to protect children, families, communities, and our planet.

4. I understand that the U.S. Environmental Protection Agency (EPA) has issued a rule entitled "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" regarding how EPA may use studies examining "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) (the "Rule"). This action establishes new restrictions on the ability of EPA to consider such dose-response data for which underlying data cannot be made "publicly available in a manner sufficient for independent validation." *Id.* at 492 (codified at 40 C.F.R. § 30.5(c)).

5. One of the main reasons I pursue my research is to improve health standards in order to lead to better health outcomes for people, particularly disadvantaged and at-risk communities. A critical motivating factor for pursuing particular lines of research is knowing that the results can contribute to new standards, particularly for chemicals and pollutants that are shown to contribute to poor health outcomes, and can receive full weight in decision-making regarding those standards. Because of EPA's regulatory authority over drinking water arsenic, nitrate and nitrites, disinfection byproducts and other contaminants, being able to make my work available to and usable by EPA is an important factor in designing and pursuing my research.

6. The nature of my work requires that I collect sensitive personal information about my study subjects. In addition to traditional personal identifiers such as name and address, I collect a wide range of deeply personal health behavior, demographic, socioeconomic, medical, and biometric data from study participants. These data are often collected from large study groups over many years. I believe the kinds of data my studies generate would be considered "dose-response data" as defined by the Rule.

7. A critical element in recruiting study subjects is my ability to promise that I can and will keep that information confidential, and that published data is "de-identified;" that is, detached from information like name and address that could link the published data to sensitive personal health or medical data from any specific individual. We have participants sign consent forms based on our promise to keep their data confidential. In addition, professional ethical standards and legal requirements further require that personal data be kept confidential. The specific and detailed procedures to protect confidentiality are set forth in the conditions required by university institutional review boards and as conditions of grants from the National Institutes of Health (NIH) and other grant-giving entities.

8. I understand that the Rule contemplates mechanisms for researchers to make data available "through restricted access in a manner sufficient for independent validation." *See* 86 Fed. Reg. 492 (codified at 40 C.F.R. § 30.5(c)). I am

not aware of any such methods that would comply with the confidentiality agreements I reach with my research subjects. This would entail seeking IRB approval can be burdensome, and if an IRB would to agree to such terms, it would take a prohibitive amount of time and resources to re-consent participants.

9. If I could not promise to keep personal data confidential in order to preserve my ability to make my study results available to—and fully considered by—EPA, I would not be able to meet my ethical and legal obligations and the quality of my research would suffer.

10. With respect to ongoing studies, I would need to seek the consent of current participants and seek approval from the appropriate institutional review boards in order to change my protocol and make confidential information publicly available—or sharable with EPA in any form—as the Rule would require for that research to receive full weight as pivotal science. I would expect a large number of participants to drop out of the study, making its results less reliable and less useful. I would also expect institutional review boards to not approve those kinds of changes due to existing legal and ethical obligations.

11. And with respect to new studies, without the promise of confidentiality it would be very difficult, if not impossible, to recruit participants. Even if I were able to recruit some participants, they would likely be fewer in number and constitute an unrepresentative sample. As a consequence, the quality and usefulness of the

research would be compromised. My research is typically based on studying large studies of the general population of the US. A small and unrepresentative study sample makes the results less relevant to the overall population and therefore less meaningful, and less useful to regulators like EPA who impose national standards.

12. These problems would make it extremely difficult to obtain funding and approval for my research. It is highly unlikely that my research would be approved by my University, the NIH, or other grant-giving entities if I could not preserve participant confidentiality or if I could not produce reliable data.

13. But if I did not adjust my research agenda to produce work that could be accorded full weight by EPA, I am still concerned that I would be unable to obtain funding. I know that an important factor in awarding NIH grants is the ability of research to have an impact on government policies and standards. If my research cannot be used to affect decision-making by EPA, NIH is less likely to fund research relevant to pollutants and substances regulated by EPA. Almost all of my research is funded through external grants coming from NIH. For example, in 2020 100% of my external funding for research I lead or jointly lead with other scientists came from NIH grants, which comprised over 95% of the total research that I lead.

14. Without NIH funding, I would not be able to carry out most of my research and the jobs of my colleagues and staff who work on NIH-funded grants

would be at risk. This currently includes 37 staff members and learners and 19 faculty members.

15. Fundamentally, I do the research I do to inform policy and improve public health. If I knew that the results of my research could not be used by EPA to make decisions to improve public health policy and lead to better health outcomes for individuals—or could not receive full weight in those decisions—there would be no reason to do that work and I would change my research priorities and/or methodologies to areas where there would not be similar impediments to my research's having an impact on improving public health policy and decisions. Adjusting my research priorities or methodologies would require me to devote time and resources to devising new methods and research priorities rather than pursuing my current research. Epidemiologic studies often take years to acquire the necessary information and measurements and to follow participants to observe their health outcomes. We have invested decades of time and money to collect valuable data to be able to address critical public health issues including emerging drinking water contaminants, air pollutants and other concerns. To switch gears at this stage would mean the impacts of my research would be significantly diminished at a time when I have the most to offer.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 8, 2021